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EXAMINER	
HINES, JANA A	

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/088,766
Filing Date: June 20, 2002
Appellant(s): KUSLYS ET AL.

Kuslys et al.
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed December 5, 2008 appealing from the Office action mailed July 14, 2008.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is substantially correct. The changes are as follows: Claims 1, 3-4, 6-10 and 13-20 are rejected under 35 U.S.C: 103(a) as being unpatentable over Yonekubo et al., (JP-002158742) in view of Georgi et al., WO 95/17102. WO 95/17102 provides priority to US Patent 5,916, 621; however US Patent 5,916,621 will be referenced as the English language version of WO 95/17102.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

JP-0021518742	Yonekubo et al.	09-1983
WO 95/17102	Georgi et al.	09-1995
5,916,621	Georgi et al.	06-1999

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3-4, 6-10 and 13-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yonekubo et al., (JP-002158742) in view of Georgi et al., WO 95/17102. WO 95/17102 provides priority to US Patent 5,916, 621; however US Patent 5,916,621 will be referenced as the English language version of WO 95/17102.

Claim 1 is drawn to a composition for an infant formula comprising: whey protein, wherein the whey protein is hydrolysed sweet whey protein from which caseino-glyco-macropeptide has been removed; casein protein; free arginine; free histidine; and a milk protein comprising 5% or more of tryptophan. Claim 3 is drawn to the composition comprising 1.5% to 3% by weight of arginine; tryptophan and histidine. Claim 4 is drawn to the composition comprising a lipid source, a carbohydrate source, and a protein source. Claim 6 is drawn to the composition wherein the whey protein is treated to remove lactose. Claim 7 is drawn to the composition comprising 6% to 50% by weight of whey protein and 20% to 40% casein protein. Claim 8 is drawn to the composition comprising 0% to 0.1% by weight histidine, 0.1% to about 0.3% by weight arginine, and 0.3 to 0.5% by weight tryptophan. Claim 9 is drawn to the composition comprising 0.2% to 0.4% by weight histidine, 1% to 2% by weight arginine, and 0.2% to 0.4% by weight tryptophan.

Claim 10 is drawn to method of producing an infant formula, the method comprising the-step-of blending whey protein, wherein the whey protein is hydrolysed sweet whey protein from which caseino-glyco-macropeptide has been removed, and casein protein together with free arginine; free histidine; and a milk protein comprising 5% or more of tryptophan, and homogenizing the blended mixture. Claim 13 is drawn to an infant formula comprising: hydrolysed sweet whey protein, from which caseino-glyco-macropeptide has been removed; casein protein; free arginine; free histidine; and a milk protein comprising 5% or more tryptophan. Claim 14 is drawn to the infant formula comprising from 9.0 to 10.0 w/w% of all protein sources contained in the infant formula.

Claim 15 is drawn to the infant formula comprising 1.5% to 3% by weight of arginine; tryptophan and histidine. Claim 16 is drawn to the infant formula comprising a lipid source, a carbohydrate source, and a protein source. Claim 17 is drawn to the infant formula comprising 6% to 50% by weight of whey protein and 20% to 40% casein protein. Claim 18 is drawn to the infant formula comprising 0.1% to 0.3% by weight arginine, and 0.3 to 0.5% by weight tryptophan. Claim 19 is drawn to the infant formula comprising 0.2% to 0.4% by weight histidine, 1% to 2% by weight arginine, and 0.2% to 0.4% by weight tryptophan. Claim 20 is drawn to a method of providing nutrition to an infant, the method comprising administering to the infant a composition comprising whey protein, wherein the whey protein is hydrolysed sweet whey protein from which caseino-glyco-macropeptide has been removed; casein protein; free arginine; free histidine; and a milk protein comprising 5% or more tryptophan.

Yonekubo et al., teach highly digestible nutritive compositions for infant use (page 2). Yonekubo et al., teach the nutritive composition comprises natural milk proteins, amino acids as the protein source and nutrients such as lipids (fats) and carbohydrates (page 2, lines 8-11). Yonekubo et al., teach casein, a tryptophan rich milk protein is at 24-32% by weight (page 2, lines 32-33). Yonekubo et al., teach the whey protein is at 30-40% by weight (page 2). Yonekubo et al., teach the whey powder obtained from the milk serum portion that is left after casein has been removed (page 3, lines 20-21). Therefore casein is removed from the whey to produce sweet whey. Yonekubo et al., teach the whey powder is further treated and lactose is eliminated from it, thereby resulting in a product useable in a nutritive infant composition (page 3, lines

21-22). Yonekubo et al., teach the composition uses highly desirable natural proteins and adds essential amino acids to fortify the proteins, thereby reducing the overall protein content (page 3, lines 2-7). Yonekubo et al., teach the composition comprising natural milk proteins and whey proteins. It is noted that the major components of such milk proteins comprise alpha-lactalbumin, a protein that has a high tryptophan content of approximately 5%.

Yonekubo et al., teach the amino acids used in the compositions are free amino acids (page 3, lines 24-25). The composition comprises histidine at 1.4 to 2.0% by weight and has tryptophan is at 0.5-0.7% by weight (page 3). It is noted that Yonekubo et al., teach different concentrations for the free arginine and tryptophan, however limitations such as different concentrations are viewed as limitations not imparting patentability. There is no evidence that these limitations provide unexpected results. The composition reduces the levels of protein ingested, provides natural proteins that are beneficial in terms of digestive absorption, succeeds in reducing total protein levels while providing supplementary essential amino acids (page 3, lines 2-5). Yonekubo et al., teach a method of making the infant formulas, see Working Example 1 wherein the ingredients are mixed together uniformly in a preparation. Yonekubo et al., teach the nutritive composition can be easily digested and utilized by babies and infants (page 2, lines 5-7). Yonekubo et al., teach in order to provide optimal emulsification and homogenization, the addition of surface active agents is necessary (page 3, lines 38-40). Yonekubo et al., teach the components are homogeneously mixed and formulated into a powder thereby yielding an infant use nutritive composition (page 4, lines 18-22).

Yonekubo et al., teach the composition is administered by dissolution in water and then administering it to an infant (page 5, lines 3-5). However Yonekubo et al., do not teach the use of hydrolysed sweet whey protein from which caseino-glyco-macropeptide has been removed.

Georgi et al, teach the importance of using whey powder/proteins that do not contain glycomacropeptide (GMP) because GMP causes the very high threonine content (col. 1-2, lines 65-2). Georgi et al., teach high threonine levels within whey proteins in infant formula causes hyperthreoninemia in infants (col. 1, lines 20-35). Georgi et al., teach the production of milk baby foods, which have whey protein as the dominant product in such foods (co1.1, lines 18-21). Georgi et al, teach milk baby foods have the disadvantage of having a high threonine content that causes high levels of threonine in the plasma of infants (col. 1, lines 20-25). Georgi et al., found that threonine content in whey powders are higher due to the addition of whey proteins (co1.1, lines 37-41). Georgi et al., teach the need for whey protein dominant milk baby food or formula with a reduced threonine content (co1.1, lines 42-45). Georgi et al, teach whey powder or whey proteins used in the production of milk baby foods are obtained exclusively from sweet whey which is produced by the precipitation and removal of caseins (col. 1, lines 51-55). Georgi et al, teach GMP must be completely removed by suitable processes; and removal processes are commercially well known (co1.2, lines 5-14). Georgi et al, teach the sweet whey after the removal GMP is further hydrolysed with enzymes according to known processes (col. 2, lines 50-52). Georgi et al., teach that with the aid of the whey protein, it is possible to increase the whey protein content

in milk baby foods to correspond with human milk and to simultaneously reduce the threonine content to 25% (col. 2, lines 42-76).

Therefore it would have been *prima facie* obvious at the time of applicants' invention to modify the sweet whey protein within the infant formula composition, along with the method of production and method of providing an infant formula as taught by Yonekubo et al., wherein the modification incorporates the use of hydrolysed sweet whey protein from which casein-glyco-macropeptide (GMP) has been removed as taught by Georgi et al., in order to use whey powder/proteins that do not contain GMP because GMP in whey proteins cause high threonine associated disorders. One of ordinary skill in the art would be motivated to modify the compositions and methods as taught by Yonekubo et al., because Georgi et al., teach that providing infant formula without high threonine levels in the whey protein is advantageous to infants; thus the claims would have been obvious because the substitution of one known element, such as sweet whey protein, for another, such as hydrolysed sweet whey, would have yielded predictable results to one of ordinary skill in the art at the time of the invention. Furthermore, the limitations drawn to the different concentrations for the arginine and tryptophan are viewed as merely optimizing the experimental parameters and not imparting patentability; thus no more than routine skill would have been required to change the concentration in the well known compositions and method of production as taught by Yonekubo et al., in view of Georgi et al. Finally, one of ordinary skill in the art would have a reasonable expectation of success since well-known commercially available methods were used to formulate, produce and administer the infant formulas

as taught by Yonekubo et al., and incorporating routinely observed in the compositions that provide infant formulas with reduced threonine content by adding hydrolysed sweet whey proteins free of GMP which as taught by Georgi et al., to achieve the claimed invention while providing a composition and methods with a reduced threonine content.

(10) Response to Argument

Appellants respectfully submit that, even if combinable, the cited references fail to disclose or suggest a milk protein comprising 5% or more of tryptophan as required, by all of the claims. However, it is the office's position that Yonekubo et al., in view of Georgi et al., teach compositions comprising natural milk proteins, whey powder, nutrients and carbohydrates. The whey powder of *Yonekubo* is a milk protein serum protein and the major serum whey proteins comprise alpha-lactalbumin, which has a high tryptophan content. It is noted that at page 13, para. 3 of the appeal brief, Appellants agree that alpha-lactalbumin is a milk protein comprising 5% or more of tryptophan. Therefore the art teaches a milk protein comprising 5% or more of tryptophan, despite Appellants' arguments.

Appellants argue that Yonekubo is entirely directed to providing essential amino acids for infants with urea cycle anomalies or nutritional disorders and does not suggest that other amino acids may be used in their free form. Contrary to appellants' statements, Yonekubo et al., clearly state that the present invention is a nutritive composition for infants and is not limited as Appellants' assert. While one of the aims of

is a nutritive composition for infant suffers of urea cycle anomalies, this aim does not affect the teaching of the ingredients of the composition or methods of preparation or provision. Therefore regardless of the aim of Yonekubo et al., composition, the same free amino acid are encompassed within the composition are disclosed.

The MPEP section 2123 teaches that patents are relevant as prior art for all they contain, "The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain." *In re Heck*, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983) (quoting *In re Lemelson*, 397 F.2d 1006, 1009, 158 USPQ 275,277 (CCPA 1968)). A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. *Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989). See also *Celeritas Technologies Ltd. v. Rockwell International Corp.,* 150 F.3d 1354, 1361,47 USPQ2d 1516, 1522-23 (Fed. Cir.1998).

Furthermore, Yonekubo et al., teach the addition of L-isoleucine, L-leucine, L-methionine, L-cystine, L-phenyalanine, L-tyrosine, L-threonine, L-tryptophan, L-valine, L-arginine and L-histidine in nutritive compositions for infants. Therefore ingredients are not added as complexes, but as free amino acids as evidenced by the L-isomer designation and individual status within the list of ingredients.

Appellants argue that not all natural milk proteins are rich in tryptophan and exemplifies beta-lactoglobulin, casein, and sodium caseinate as containing less than % of tryptophan and that Yonekubo does not disclose a milk protein comprising 5% or more of tryptophan merely because it teaches a composition comprising natural milk proteins. However alpha-lactalbumin, is a milk protein with a high tryptophan content; and Appellant agrees that alpha-lactalbumin is a milk protein comprising 5% or more of tryptophan. Furthermore, another milk protein is serum albumin, which is rich in tryptophan. It is irrelevant that beta-lactoglobulin comprises a larger portion of the whey protein, since the claims only a milk protein with 5% or more tryptophan and alpha-lactoglobulin meets that limitation. It is noted that neither the claims nor specification state what specific milk protein is comprised in the instantly claimed composition, which would allow for an appropriate comparison. Yonekubo et al., teach milk proteins such as alpha-lactoferrin a well known milk protein as having 5% or more of tryptophan, contrary to Appellants repeated assertions to the contrary.

Appellants submit that the cited combination would render Yonekubo unsatisfactory for its intended purpose and that there is no suggestion or motivation to make the proposed modification. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine,* 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir.

1988) and *In re Jones,* 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, one of ordinary skill in the art would be motivated to modify the compositions and methods as taught by Yonekubo et al., because Georgi et al., teach that providing an infant composition with hydrolysed sweet whey protein from which caseino-glyco-macropeptide (GMP) is advantageous and one of ordinary skill in the art would be motivated to prevent hyperthreoninemia in infants which is caused by high threonine levels in whey protein which is a component of infant compositions. Furthermore, no more than routine would have been required to modify the composition and method of Yonekubo et al., by incorporating the hydrolysed sweet whey when Yonekubo et al., and Georgi et al., teach that the removal of casein-glyco-macropeptide and the hydrolysis of sweet whey are performed by used well known processes and desirable in infant formulations.

Appellants submit that *Yonekubo* teaches away from whey proteins that contain reduced levels of threonine. It is also Office's position that disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. *In re Susi,* 440 F.2d 442, 169 USPQ 423 (CCPA 1971). "A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." *In re Gurley,* 27 F.3d 551,554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994). Therefore contrary to applicants' argument, the prior art does not teach away from the instant claims, rather the references teach the need to reduce the threonine content, not eliminate the threonine content. It is noted that the need for reduced threonine levels does not equate

to compositions not having any threonine content as Appellants argue. The teachings of Yonekubo et al., where threonine is added does not discount the use of sweet whey protein which Yonekubo et al., nor does it teach away from incorporating hydrolysed sweet whey from which caseino-glyco-macropeptide has been removed as taught by Georgi et al.

Appellants assert Yonekubo et al., is unconcerned with a whey protein that contains reduced threonine like Georgi et al., and that Yonekubo et al., is concerned with urea anomalies and nutritional disorders. It is noted that hyperthreoninemia results when high threonine levels cause the formation of too much urea and results in ammonia toxicity in the body. Therefore hyperthreoninemia would qualify as a urea anomaly that Yonekubo et al., would likely be concerned with contrary to Appellants arguments. Furthermore, hyperthreoninemia would be a nutritional disorder. Therefore, Appellants argument should not be found persuasive.

Appellants assert that the mere disclosure in *Yonekubo* of combining additional threonine with its whey protein that already has a high threonine content teaches away from whey proteins that contain reduced levels of threonine. However, the MPEP section 2123 teaches that patents are relevant as prior art for all they contain, the use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain. *In re Heck,* 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983) (quoting *In re Lemelson,* 397 F.2d 1006, 1009, 158 USPQ 275, 277 (CCPA 1968)). Therefore a reference may be relied upon for

all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. *Merck & Co. v. Biocraft Laboratories,* 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989). In this case, Appellants' argument is not persuasive especially when considering that one of ordinary skill in the art knew that high threonine levels in infants causes hyperthreoninemia; Yonekubo et al., is concerned with urea anomalies and addressing nutritional disorders; Georgi et al., teach milk baby foods have the disadvantage of having a high threonine content in whey proteins; and both references disclosed the desire to be similar to breast milk.

Appellants argue that because Yonekubo et al., add threonine as one of the essential amino acids to its composition, Yonekubo et al., teach away from Georgi et al. However, Georgi et al., clearly and specifically points to the threonine content in whey powders. Georgi et al., teaches the removal of threonine found in whey proteins and thereby teaches the removal of GMP. Despite Appellants assertions, Georgi et al., is specifically concerned with reducing threonine levels in whey protein, and not removing all threonine from the infant compositions. Georgi et al., clearly teach the need for some threonine, by pointing out that threonine is found in human milk. Furthermore, Georgi et al., teach the desire to have the infant composition mimic human milk as closely as possible by having a similarly theronine content. Furthermore, Quero et al., [Journal of Pediatric Gastroenterology and Nutrition. 1997. Vol. 24(4): 491], teach the incidence of hyperthreoninemia is reduced by feeding infants whey predominant formula without GMP. Quero et al., clearly states that threonine concentrations are still found in GMP-free formula and in breast milk. Thus Appellants' argument that the addition of threonine

would negate the effects of reduced threonine when protein should not be found persuasive, since infant formula and breast milk clearly contains threonine, a required amino acid.

Appellants argue that Yonekubo et al., teach sweet whey protein and not hydrolysed sweet whey protein. In response to applicant's arguments against the Yonekubo et al, reference individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Finally, Appellants argue that the Patent Office has failed to consider the cited references as a whole including those portions teaching against or away from each other and/or the claimed invention. However, the Office asserts that the test is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). In this case, all of the claimed elements were known in the prior art and one of ordinary skill in the art could have incorporated the hydrolysed sweet whey protein with GMR removed as claimed by known methods with no change in the respective function of the sweet whey protein, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Therefore, Appellants' arguments should not be found persuasive and the rejection should be maintained.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/JaNa Hines/

Examiner, Art Unit 1645

Conferees:

/Robert B Mondesi/

Supervisory Patent Examiner, Art Unit 1645

/Jeff Stucker/

Supervisory Patent Examiner, Art Unit 1649